

APPENDIX A¹

C.I. Pigment Violet 29: List of Publicly Available Study Reports²

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ³
CBI claim fully withdrawn (Full study report)	1. Summary of toxicological investigations with CAS 81-33-4, 1.5 Eye Irritation Study. HERO ID: 4731519	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/3/?documentUUID=355c6cab-5b7e-417f-b083-4c3a890c339e					
CBI claim fully withdrawn (Full study report)	2. Summary of toxicological investigations with CAS 81-33-4, 2.5 Eye Irritation Study. HERO ID: 4731520	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/3/?documentUUID=123b8854-6e8f-4482-9e03-183d6380fcf8					

¹ Attachment A of BASF C&E GmbH's substantiation cites 12 studies for which the company makes no confidentiality claims. However, one of the study citations ("BASF. (1975c). Eye irritation / corrosion," listed as entry 3 in the second list on Substantiation Attachment A), which was based on a citation EPA published in Appendix D on page 42 of its draft PV29 risk evaluation, does not correspond to any study. The citation in EPA's draft risk evaluation was an error, which EPA intends to correct in its final risk evaluation. Accordingly, the CBI determination reflects that there are 11, not 12, full study reports in which BASF held an interest and relinquished any CBI claims to.

² The 24 study reports represent the following disciplines: #1-17 Human Health; #18-20 Environmental Hazard; #21-22 Environmental Fate, and #23-24 Physical Chemical properties. Study reports #1-13 and #18 were translated from German.

³ ECHA Robust summaries were published to the docket at the following link: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002>

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ³
CBI claim fully withdrawn (Full study report)	3. Perylimid ⁴ Testing the acute dermal irritant effects/caustic effects on rabbits. HERO ID: 4731534	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Hoechst Pharma Research Toxicology, Germany. Report No. 84.0228 (OECD- 404 skin irritation;	No ⁵
CBI claim fully withdrawn (Full study report)	4. Perylimid Testing the acute irritant effects/caustic effects on the rabbit eye. HERO ID: 4731524	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Hoechst Pharma Research Toxicology, Germany. Report No. 84.0229 OECD-405; eye irritation)	No
CBI claim fully withdrawn (Full study report)	5. Summary of toxicological investigations with CAS 81-33-4, 1.2 Acute inhalation toxicity with rats. HERO ID 4731525	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes

⁴ Perylimid-German name for pigment violet

⁵ Summarized below are the four additional full study reports that were not described in the ECHA database.

- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion
- OECD Guideline 209: Determination of the inhibition of oxygen consumption by activated sludge

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ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=2baa5685-0c63-41a2-88e0-6539146fda83					
CBI claim fully withdrawn (Full study report)	6. Summary of toxicological investigations with CAS 81-33-4, 2.2 Acute inhalation toxicity with rats. HERO ID: 4731526	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=2064a5d4-7557-4aed-b389-59bae4eb97d7					
CBI claim fully withdrawn (Full study report)	7. Summary of toxicological investigations with CAS 81-33-4, 1.3 Acute intraperitoneal toxicity with mice. HERO ID: 4731527	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/5/?documentUUID=38e65d5f-6d87-4037-9153-a2a123481983					
CBI claim fully withdrawn (Full study report)	8. Summary of toxicological investigations with CAS 81-33-4, 2.3 Acute intraperitoneal toxicity with mice. HERO ID: 4731528	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/5/?documentUUID=7eed1bdb-9d2c-44ab-9d49-ccb48bfe7ec2					

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ³
CBI claim fully withdrawn (Full study report)	9. Summary of toxicological investigations with CAS 81-33-4, 1.1 Acute oral toxicity with rats. HERO ID: 4731529	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/2/?documentUUID=e73c9b1a-2e30-4c7b-856f-be9c27b62e3a					
CBI claim fully withdrawn (Full study report)	10. Summary of toxicological investigations with CAS 81-33-4, 2.1 Study report for CAS 81-33-4, Acute oral toxicity with rats. HERO ID: 4731530	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/2/?documentUUID=2627a9d8-85f8-408a-8a92-7db3e9edbc32					
CBI claim fully withdrawn (Full study report)	11. Testing the acute oral toxicity in the male and female Wistar rat. HERO ID: 4731531	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Report No. 84.0225 (OECD-401)	No
CBI claim fully withdrawn (Full study report)	12. Summary of toxicological investigations with CAS 81-33-4, 1.4 Skin irritation study. HERO ID: 4731532	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/2/?documentUUID=991935ed-8813-45d4-a578-e985e45529c7					

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CBI claim fully withdrawn (Full study report)	13. Summary of toxicological investigations with CAS 81-33-4, 2.4 Skin irritation study. HERO ID: 4731533	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/2/?documentUUID=787aa890-cd18-4595-832b-7cc30e58641b					
CBI claim fully withdrawn (Full study report)	14. Perylimid Study of the Mutagenic Potential in Strains of <i>Salmonella Typhimurium</i> (Ames Test) and <i>Escherichia coli</i> . HERO ID: 4731535	Jung, R., Weigand, W	1983	FDA (Food Additive Petition) (Clariant, Germany filing)	Hoechst Aktiengesellschaft, Germany. Report No. 83.0695	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/7/2/?documentUUID=029bc6b6-17f3-49df-8a18-d363003217df					
CBI claim partially withdrawn (Redacted copy)	15. Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT) With Paliogen Violet 5011. HERO ID: 4731536	Wollny, H	2012	Sun Chemical (The Netherlands)	Harlan Cytotest Cell Research GmbH, Germany. Report No. 1443105.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/7/2/?documentUUID=ce0e96f3-e018-4a7e-bbfc-07cfdbbc2b9e					
CBI claim partially withdrawn (Redacted copy)	16. Perylimid F: Local Lymph Node Assay. HERO ID: 4731537	Johnson, I.R.	1999	Sun Chemical (The Netherlands)	Central Toxicology Laboratory, UK. Project No. CTL/P/6194 (OECD-406)	Yes

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ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/5/2/?documentUUID=a548f01b-ceec-4805-8bac-9d5b1126db46					
CBI claim partially withdrawn (Redacted copy)	17. Reproduction/developmental Toxicity Screening Test in Wistar Rats Oral Administration (Gavage). HERO ID: 4731538	Stark, D., Treumann, S., Van Ravenzwaay, B	2013	Sun Chemical (The Netherlands)	BASF SE, Germany. Project No. 80R0223/11C162 (OECD-421)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/9/2/?documentUUID=9a37a3a9-d311-48a2-a34b-6359b6bef6e0					
CBI claim fully withdrawn Full study report	18. Perylimid Testing the acute toxicity in the fish model Zebra danio (<i>Brachydanio rerio</i>) over the course of 96 hours. HERO ID: 4731539	Market, D.I. Jung, R.	1988	Clariant (Germany)	Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. (OECD-203)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/2/?documentUUID=975f8535-c960-4857-b6c3-596d913e5461					
CBI claim partially withdrawn (Redacted copy)	19. Paliogen Violet 5011, <i>Lemna gibba</i> L., CPCC 310 Growth Inhibition Test. HERO ID: 4731540	BASF	2012	Sun Chemical (The Netherlands)	Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. Pszczyna, Poland (OECD-221)	Yes

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ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/7/?documentUUID=396286a2-97c2-4f76-97e0-6dfd58eb90bc					
CBI claim partially withdrawn (Redacted copy)	20. Paliogen Violet 5011, <i>Daphnia magna</i> , Acute immobilization test. HERO ID: 4731541	BASF	2012	Sun Chemical (The Netherlands)	Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May, 2012), Pszczyna, Poland. (OECD- 202)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/4/?documentUUID=983ec9ec-9efc-4350-9a86-b6c1f572f5ba					
CBI claim partially withdrawn (Redacted copy)	21. Determination of the Inhibition of Oxygen Consumption by Activated Sludge by Perylimid F in the Activated Sludge Respiration Inhibition Test according to GLP, EN 45001 and ICO 9002. HERO ID: 4731542	BASF	1999	Sun Chemical (The Netherlands)	Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (OECD-209)	No
CBI claim partially withdrawn (Redacted copy)	22. Determination of the Biodegradability of Perylimid F in the Manometric Respirometry Test according to GLP, EN 45001 and ISO 9002. HERO ID: 4731543	BASF	1999	Sun Chemical (The Netherlands)	Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (OECD 301-F)	Yes

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ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/5/3/2/?documentUUID=c6149dae-22a5-4dda-85f4-34da02afc03f					
CBI claim partially withdrawn (Redacted copy)	23. Physical-Chemical properties of “Paliogen Violet 5011” (LogKOW) ⁶ HERO ID: 4731544	BASF	2013	Sun Chemical (The Netherlands)	BASF Study No. 11L00105	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/4/8/?documentUUID=53829854-0728-48dd-9184-2045facf18f2					
CBI claim partially withdrawn (Redacted copy)	24. Physical-Chemical properties of “Paliogen Violet 5011” (Melting point) ⁵ . HERO ID: 4731544	BASF	2013	Sun Chemical (The Netherlands)	BASF Study No. 11L00105	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/4/3/?documentUUID=0ed13da2-4ef1-4d4e-b923-4d6b88bc38a2					

⁶ BASF C&E GmbH’s CBI substantiation treated this citation as one study (“BASF 2013 study report. Physical-chemical properties of Paliogen Violet 5011. Study No. 11L00105,” listed as entry 7 in the first list on Substantiation Attachment A). EPA’s draft risk evaluation for PV29 treats this study as two separate full study reports that share a cover page. Accordingly, for purposes of this CBI determination, EPA will continue to treat that submission as two separate full study reports.